## REMARKS

The claims have been amended to better define the claimed invention and better distinguish the claimed invention from the prior art. More particularly, independent claim 1 has been amended to specify that the controlled release of the pharmaceutical ingredients is at two or more different selected sites within the patient's alimentary canal. Independent claim 5 has been similarly amended. Independent claim 21 has been amended to drop reference to the mixture of Omeprazole and Clarithoromycin. Additionally, new claim 22 has been added which combines the subject matter of claims 13-16 and 18-20 which were indicated to be allowable over the art.

The several art rejections are believed to be in error. Considering first the rejection of claims 1, 3, 4, 8, and 12 under 35 USC §102(b) as being anticipated by Mlodozeniec et al. (US Patent No. 4,069,084), claim 4 was canceled in the previous amendment and incorporated into the independent claims to address the Examiner's previous objections. Mlodozeniec et al. teaches a method of affixing agents to a web in order to circumvent the need and cost of the use of "pharmaceutical adjunct materials" (Mlodozeniec et al. at column 3, line 19). Mlodozeniec et al. also teaches that sealing the web with a substance such as ethylcellulose will allow for the invention to function as a sustained release (Mlodozeniec et al. at column 5, lines 40-47). A sustained release provides release relative to time, whereas a controlled release as claimed by the present invention provides release to two or more selected sites within a patients alimentary canal. Mlodozeniec et al. does not teach this. Mlodozeniec et al. merely teaches sustained release, whereas the present invention's ingestible membrane with a selectable permeable porosity enables delivery of pharmaceuticals at two or more specific sites along the alimentary

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canal (see specification at page 13, line 14 to page 14, line 4). Furthermore, the method by which Mlodozeniec et al. achieves sustained release is not determined by the porosity of the web, but by encapsulating a "fan-folded" web in a gastric-acid resistant substance, thus allowing for "gradual erosion" (see Mlodozeniec et al. at column 5, lines 41-46). Mlodozeniec et al. therefore fails to anticipate the invention as claimed in amended claim 1, as well as in claims 3, 8, and 12, which depend thereon.

Turning to the rejection of claims 1, 3, 4, and 8-12 under 35 USC §103(a) as being unpatentable over Mlodozeniec et al. in view of Pletcher et al. (US Patent No. 6,074,688), as noted supra claim 4 was canceled in the previous amendment and incorporated into the independent claims to address the Examiner's previous objections. The deficiencies of Mlodozeniec et al. vis-á-vis claim 1 and the several claims dependent thereon are discussed above. Pletcher et al. does not supply the missing teachings. Pletcher et al. teaches a method of electrostatically depositing dry powder on a substrate. The Examiner relies on Pletcher et al. to supply the missing teaching from Mlodozeniec et al. that the web is formulated into a tablet or capsule. Pletcher et al. however only teaches that the tablet is coated if the tablet material cannot retain a corona charge, not that the pharmaceutical agent is deposited on a web and encapsulated in the tablet (see Pletcher et al. at column 5, lines 53-56). Mlodozeniec et al. actually teaches away from encapsulating the web, stating that "in most instances, there is no coating per se applied to the finished dosage form" (Mlodozeniec et al. at column 4, lines 66-67). Neither Mlodozeniec et al. nor Pletcher et al. teaches or suggests encapsulating the web in a tablet. More significantly, Pletcher et al. does not supply the missing teaching that an ingestible membrane have a selectable permeable porosity to enable site specific delivery of pharmaceuticals at two or more sites along the alimentary canal as required by amended claim

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1. Therefore, no combination of Mlodozeniec et al. and Pletcher et al. would achieve the present invention as claimed in claim 1, or in claims 3 and 8-12, which depend thereon.

Turning to the rejection of claim 5 under 35 USC §103(a) as being unpatentable over Mlodozeniec et al. in view of Lerner et al. (US Patent No. 6,197,331), claim 5, like claim 1, specifies delivery at two or more sites within the alimentary canal. Mlodozeniec et al. doesn't teach this. The Examiner relies on Lerner et al. to teach a drug-containing layer and an adhesive layer. Lerner et al. teaches an oral patch that adheres to the teeth to provide topical release of a pharmaceutical agent to the teeth. Claim 5 requires adhesion within the alimentary canal, not at the entrance to the alimentary canal. More significantly, Lerner et al. does not teach an ingestible membrane with selectable permeable porosity for site specific delivery at two or more sites within the alimentary canal. Thus, Lerner et al. does not supply the missing teachings of Mlodozeniec et al. to render claim 5 obvious.

Turning to the rejection of claims 17 and 21 under 35 USC §103(a) as being unpatentable over Mlodozeniec et al. in view of Sanso (US Patent No. 6,350,468), considering first claim 17, claim 17 depends on claim 1. The deficiencies of Mlodozeniec et al. vis-a-vis claim 1 are discussed above. The Examiner relies on Sanso to teach a combination of Omeprazole and Clarithromycin. However, Sanso does not teach or suggest site-specific delivery, at two or more sites within the alimentary canal as required by claim 1. Thus, no combination of Mlodozeniec et al. and Sanso would achieve or render obvious claim 1or claim 17, which depends thereon. As to claim 21, claim 1 has been amended to delete reference to a mixture of Omeprazole and Clarithoromycin. Since Sanso fails to teach any of the other mixtures specified by claim 21, it is submitted no combination of Mlodezeniec et al. and Sanso reasonably could be said to achieve claim 21.

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Turning to the rejection of claims 1, and 3-12 under 35 USC §103(a) as being unpatentable over Sturzenegger et al. (US Patent No. 4,197,289) in view of Mlodozeniec et al., claim 4 was canceled in the previous amendment and incorporated into the independent claims to address the Examiner's previous objections. The Examiner relies on Sturzenegger et al. to teach an edible web that pharmaceutical agents can be deposited on. Sturzenegger et al. teaches loading of a pharmaceutical ingredient on to an edible web and then sealing to completely internalize each layer. Sturzenegger et al. also teaches a sustained release, whereby the release rate can be manipulated by the web's thickness, composition, tightness and if there is an overwrap or seal (see Sturzenegger et al. at column 5, lines29-35). Sturzenegger et al., like Mlodozeniec et al., teaches sustained release through fan-folding the web and encapsulating the web in a material such as ethylcellulose (see Sturzenegger et al. at column 5, lines 44-51). Sturzenegger et al. like Mlodozeniec et al. fails to teach or suggest an ingestible membrane with selectable permeable porosity to enable site-specific delivery along two or more selected sites within the alimentary canal as required by claim 1. Thus, no combination of Sturzenegger et al. and Mlodozeniec et al. would achieve ro render obvious claim 1, and neither claim 1, nor claim 3, and claims 5-12 which depend thereon, can be said to be obvious from any combination of Sturzenegger et al. and Mlodozeniec et al.

Having dealt with all the objections raised by the Examiner, the Application is believed to be in order for allowance. Early and favorable action is respectfully requested.

Enclosed is Form PTO-2038 in the amount of $200.00 to cover the cost of one added independent claim.

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Respectfully submitted,

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